Individual Case Safety Report

11516262-01-00-01

CBER

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See PRA statement on reverse.

.Y reporting of
uct problems and
ic errors

1 of 2

FDA USE ONLY

Triage unit sequence #

614964

Adverse Event Reporting Program

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	74 years old	☑ Female ☐ Male	145 lb or 65.9 kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
☑ Death: (b) (6) *(mm/dd/yyyy)*
☐ Life-threatening
☐ Hospitalization - initial or prolonged
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
☐ Disability or Permanent Damage
☐ Congenital Anomaly/Birth Defect
☐ Other Serious (Important Medical Events)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
07/2015	09/03/2015

5. Describe Event, Problem or Product Use Error

Patient was screened for the fecal microbiota transplant study 06-APR-2015, and completed the fecal microbiota transplant procedure on 27-MAY-2015 using a related donor. The 24-hour follow-up phone call was completed with the patient's son. At the 24-hour follow-up phone call, patient's son reported that the patient was experiencing a mild diarrhea. The patient's son answered negatively for abdominal pain, hospitalization, fevers, chills, fatigue, loss of appetite, and constipation. The 7-day follow-up phone call was also completed with the patient's son on 04-JUN-2015. At the 7-day follow-up phone call, the patient's son reported that the patient was...

6. Relevant Tests/Laboratory Data, Including Dates

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*

History of Leukemia,
Chronic obstructive pulmonary disease
Colon cancer resulting in resection and colostomy
Osteoarthritis of the hips
Right hip fracture requiring surgery
Bowel obstruction
Hypertension
Left arm fracture

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*

☐ Yes ☑ No ☐ Returned to Manufacturer on: _____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*

#1 Name:
Strength:
Manufacturer:

#2 Name:
Strength:
Manufacturer:

2. Dose or Amount	Frequency	Route
#1 300 ml	once	colonoscopy
#2		

3. Dates of Use *(if unknown, give duration) from/to (or best estimate)*

#1 05/27/2015
#2

4. Diagnosis or Reason for Use *(Indication)*

#1 Recurrent C. Difficile Infection
#2

5. Event Abated After Use Stopped or Dose Reduced?

#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☑ Doesn't Apply

8. Event Reappeared After Reintroduction?

#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☑ Doesn't Apply

6. Lot #	7. Expiration Date
#1	#1
#2	#2

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name: Fecal Microbiota Transplant

2. Common Device Name: Stool Transplant

2b. Procode: CTU

3. Manufacturer Name, City and State: (b) (6), (b) (4)

SEP 16 2015

4. Model #	Lot #	5. Operator of Device
N/A	N/A	☑ Health Professional
Catalog # N/A	Expiration Date *(mm/dd/yyyy)* N/A	☐ Lay User/Patient ☐ Other:
Serial # N/A	Unique Identifier (UDI) # N/A	

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*
05/27/2015	

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☑ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

Amiodarone (historic medication)
Lisinopril (historic medication)

G. REPORTER *(See confidentiality section on back)*

(b) (6), (b) (4)

15

2. Health Professional?	3. Occupation	4. Also Reported to:
☑ Yes ☐ No	Physician	☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☐

PLEASE TYPE OR USE BLACK INK

Individual Case Safety Report

11516262-01-00-02

ON PAGE)
Y reporting of
roduct problems

Adverse Event Reporting Program

B.5. Describe Event or Problem *(continued)*

experiencing moderate fatigue, mild loss of appetite, and moderate diarrhea. The patient's son answered negatively for abdominal pain, hospitalization, fever, and chills. Patient's son reported that the diarrhea had "gotten better". Patient and her son did not have any questions or concerns at this time. Due to the patient and clinic scheduling conflict, patient's 4-week follow-up appointment was not scheduled until 20-JUL-2015. No other adverse events were reported by the patient or patient's son during this time. Site became aware of patient's death when son called to cancel the scheduled the 4-week follow-up appointment on 20-JUL-2015 (approximately 2 months after the fecal transplant procedure). No medical information is available regarding the patient's death, for the medical records are at another hospital. Dr. (b) (6) and Dr. (b) (6) both called the patient's son to request additional information about the patient's death and obtain hospital records related to the patient's death, and neither of them were not able to reach the patient's son. Due to the patient's ongoing comorbidities noted during the screening visit and considering that 2 months had passed before the patient's death, investigators felt that the patient's death was not related to the FMT procedure. This report will be updated as more information becomes available.

B.6. Relevant Tests/Laboratory Data, Including Dates *(continued)*

B.7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)* *(continued)*

Allergic to amoxicillin

F. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)* *(continued)*

Lorazepam (historic medication)
Sertraline (historic medication)
Folic acid (historic medication)
Aspirin 81mg (historic medication)
Calcium Carbonate-Vita D-Mineral (historic medication)
Dasatinib (historic medication)
Potassium Choloride (historic medication)
Furosemide (historic medication)
Fluticason-salmeterol (historic medication)
Levetiracetam (historic medication)
Metoprolol (historic medication)

Professional Report OBER

Form Approved: OMB No. 0910-0291, Expires: 12/31/2011
See OMB statement on reverse.

Individual Case Safety Report

11789390-01-00-01

:porting of problems and rors

FDA USE ONLY

Triage unit sequence #

42 16256062

	Dose or Amount	Frequency	Route
#1		once	Oral
#2			

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	52 Years (b) (6)	☑ Female ☐ Male	____ lb or 65 kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem (e.g., defects/malfunctions)
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event (Check all that apply)
☐ Death: ____ (mm/dd/yyyy) ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - initial or prolonged ☑ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Dates of Use (If unknown, give duration) from/to (or best estimate)
#1 11/24/2015 - 11/24/2015
#2

4. Diagnosis or Reason for Use (Indication)
#1 recurrent C. diff infection
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☑ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #
#1
#2

7. Expiration Date
#1 05/05/2016
#2

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC # or Unique ID
(b) (6)

3. Date of Event (mm/dd/yyyy)	4. Date of this Report (mm/dd/yyyy)
11/24/2015	11/25/2015

5. Describe Event, Problem or Product Use Error

See additional page(s) for complete text.

6. Relevant Tests/Laboratory Data, Including Dates

See additional page(s) for complete text.

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)

See additional page(s) for complete text.

C. PRODUCT AVAILABILITY

Product Available for Evaluation? (Do not send product to FDA)

☐ Yes ☑ No ☐ Returned to Manufacturer on: ____ (mm/dd/yyyy)

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer (from product label)

#1 Name: fecal microbiota preparation
Strength:
Manufacturer: DSS

#2 Name:
Strength:
Manufacturer: NOV 30 2015

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name CTU

3. Manufacturer Name, City and State NOV 30 2015

4. Model #	Lot #	5. Operator of Device
		☐ Health Professional
Catalog #	Expiration Date (mm/dd/yyyy)	☐ Lay User/Patient
		☐ Other:
Serial #	Other #	

6. If Implanted, Give Date (mm/dd/yyyy)

7. If Explanted, Give Date (mm/dd/yyyy)

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

See additional page(s) for complete text.

G. REPORTER (See confidentiality section on back)

(b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☑ Yes ☐ No		☑ Manufacturer
		☐ User Facility
5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☑		☐ Distributor/Importer

PLEASE TYPE OR USE BLACK INK

Individual Case Safety Report

11789390-01-00-02

6256662

Patient received stool transplant product - Openbiome fecal microbiota preparation at 13:00 on 11/24 - and developed fever and WBC to 30 by 23:00. Patient previously stable. Possible connection to drug, not certain.

B.6. **Relevant Tests/Laboratory Data, Including Dates** *(continued)*

11/24 23:15 temperature 101.3F, 11/24 23:59 WBC 30.9 ANC 26.8

B.7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)*

Chronically ill, ventilated long term subacute patient with recurrent C. diff from years of chronic antibiotic use for multidrug resistant organisms.

F. Concomitant Medical Products and Therapy Dates (Exclude treatment of event) *(continued)*

Scheduled Description Status Route &n bsp; Frequency Start End R/O D/C *Rx Communication - Vaccine administration reminder Dispensed Commun ONCE (UNSCHEDULED) 10/01 0751 -- R/O &n bsp; D/C *tobramycin Pharmacy Dosing Order Verified Commun &nbs p; PHARMACY PROTOCOL 11/25 0659 -- R/O &n bsp; D/C artificial tears (LUBRIFRESH P.M.) Ophth Oint Dispensed BOTH CONJUNC BID 06/22 2100 -- R/O &n bsp; D/C atorvastatin (LIPITOR) Tab 80 mg Verified PEG TUBE EVERY BEDTIME 11/03 2100 -- R/O &n bsp; D/C cefepime (MAXIPIME) 1g in 0.9% NaCl 50mL IVPB (minibag) Dispensed IV &nb sp; Q8HR 11/25 0000 -- R/O &n bsp; D/C chlorhexidine (PERIDEX, PERIOGARD) 0.12% Oral Soln 5 mL Dispensed TOPICAL ORAL Q12H 06/22 2100 -- R/O &n bsp; D/C famotidine (PEPCID) Tab 20 mg Verified GTUBE &n bsp; BID 11/25 2100 -- R/O &n bsp; D/C levETIRAcetam (KEPPRA) 100mg/mL Oral Soln 250 mg Dispensed GTUBE & nbsp; Q12HR 06/22 2130 -- R/O &n bsp; D/C polyvinyl alcohol (AKWA TEARS) 1.4% Ophth Soln 1 Drop Dispensed BOTH EYES TID 06/22 1715 -- R/O &n bsp; D/C tobramycin 120 mg in NaCl 0.9% 100 mL IVPB Dispensed IV &n bsp; Q8HR 11/25 1000 -- R/O &n bsp; D/C PRN Description Status Route & nbsp; Frequency Start ; End R/O D/C albuterol 0.083% Neb Soln 2.5 mg Verified ORAL INHALAT Q2H PRN 06/22 1702 -- R/O &n bsp; D/C bisacodyl (DULCOLAX) Supp 10 mg Dispensed PR &nbs p; DAILY PRN 06/22 1702 -- R/O &n bsp; D/C glycopyrrolate (ROBINUL) Tab 1 mg Dispensed PO &nbs p; TID PRN 10/27 1808 -- R/O &n bsp; D/C midodrine (PROAMATINE) Tab 5 mg Dispensed PEG TUBE Q6H PRN 09/18 1417 -- R/O &n bsp; D/C sodium phosphates (FLEET) 1 Enema Dispensed PR & nbsp; DAILY PRN 06/22 1702 -- R/O &n bsp; D/C Continuous Description Status Route & nbsp; Frequency Start ; End R/O D/C NaCl 0.45% IV Soln Verified IV &nb sp; CONTINUOUS 11/25 0715 -- R/O &n bsp; D/C

11809820-01-00-01

CBER

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See PRA statement on reverse.

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

VOLUNTARY reporting of adverse events, product problems and product use errors

Page 1 of 7

FDA USE ONLY
Triage unit sequence #: 627023

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	59	☒ Female ☐ Male	100 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☐ Adverse Event ☐ Product Problem (e.g., defects/malfunctions)
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event (Check all that apply)
☒ Death: _____ (mm/dd/yyyy) ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - initial or prolonged ☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (mm/dd/yyyy)	4. Date of this Report (mm/dd/yyyy)
11-6-15	12-3-15

5. Describe Event, Problem or Product Use Error

Product use went well with no serious adverse effects. Pt. expired (b) (6) to other problems (see next form).

6. Relevant Tests/Laboratory Data, Including Dates

CTU

DEC – 7 2015

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)

Hx. Ca Ovary, Pulat. leg amputations, seizures, CVA, DM

C. PRODUCT AVAILABILITY

Product Available for Evaluation? (Do not send product to FDA)
☐ Yes ☐ No ☐ Returned to Manufacturer on: _____ (mm/dd/yyyy)

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer (from product label)
#1 Name: Fecal Transplant product (b) (6)
Strength:
Manufacturer: open Biom...
#2 Name:
Strength:
Manufacturer:

2. Dose or Amount	Frequency	Route
#1 30 ml	X1	upper endoscopy
#2		

3. Dates of Use (If unknown, give duration) from/to (or best estimate)	5. Event Abated After Use Stopped or Dose Reduced?
#1 11-6-15	#1 ☐ Yes ☐ No ☒ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply
4. Diagnosis or Reason for Use (Indication) #1 clostridium Difficile #2	8. Event Reappeared After Reintroduction? #1 ☐ Yes ☐ No ☒ Doesn't Apply #2 ☐ Yes ☐ No ☐ Doesn't Apply
6. Lot # #1 (b) (6) #2	7. Expiration Date #1 #2
	9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name
2. Common Device Name
2b. Procode
3. Manufacturer Name, City and State
4. Model #
Lot #
5. Operator of Device ☐ Health Professional ☐ Lay User/Patient ☐ Other:
Catalog #
Expiration Date (mm/dd/yyyy)
Serial #
Unique Identifier (UDI) #
6. If Implanted, Give Date (mm/dd/yyyy)
7. If Explanted, Give Date (mm/dd/yyyy)
8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? ☐ Yes ☐ No
9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

G. REPORTER (See confidentiality section on back)

(b) (6)

DSS

07 2015

☒ Yes ☐ No RN

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☐

4. Also Reported to:
☐ Manufacturer
☐ User Facility
☒ Distributor/Importer

PLEASE TYPE OR USE BLACK INK

FORM FDA 3500 (2/13) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

627023

11809820-01-00-02

UATION PAGE)

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

For VOLUNTARY reporting of adverse events and product problems

B.5. Describe Event or Problem *(continued)*

Pt. developed C. Difficile infection and was non-responsive to medication. A fecal transplant was performed on 11/6/15 via upper endoscopy. Her diarrhea resolved within a few days. Pt was nutritionally depleted so tube feedings were in progress. About 2 weeks post procedure, she developed a probable small bowel obstruction + frequent emesis. She developed Pneumonia + resp. failure. She subsequently expired on (b) (6)

B.6. Relevant Tests/Laboratory Data, Including Dates *(continued)*

A repeat colonoscopy on 11/24 showed no signs of recurrent infection and she had no further diarrhea.

B.7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)* *(continued)*

F. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)* *(continued)*

Individual Case Safety Report

11870841-01-00-01

ıRY reporting of
ıduct problems and
use errors

e 1 of 1

Form Approved: OMB No. 0910-0291, Expires: 8/30/2015
See PRA statement on reverse.

FDA USE ONLY

Triage unit sequence #

629815

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6)	73	☒ Female ☐ Male	___ lb or 78 kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☒ Adverse Event ☐ Product Problem (e.g., defects/malfunctions)
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event (Check all that apply)

☐ Death: ___ (mm/dd/yyyy) ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☒ Hospitalization - initial or prolonged ☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (mm/dd/yyyy): 12/20/2015

4. Date of this Report (mm/dd/yyyy): 12/23/15

5. Describe Event, Problem or Product Use Error

Pt admitted c severe C-diff colitis, treated with Flagyl, Vancomycin - these were stopped 24h. Pt received Fecal microbiota transplant 12/16/15. Improved D/C (b) (6) Readmit (b) (6) with ABD pain, fever, hypotension

6. Relevant Tests/Laboratory Data, including Dates

(b) (6) CT scan - significant colitis of entire colon
WBC 36.4 (b) (6) WBC 11 (b) (6)

7. Other Relevant History, including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)

Hx of CAD, DM c gastroparesis, renal insufficiency

C. PRODUCT AVAILABILITY

Product Available for Evaluation? (Do not send product to FDA)

☐ Yes ☒ No ☐ Returned to Manufacturer on: ___ (mm/dd/yyyy)

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer (from product label)

#1 Name: Fecal microbiota preparation
Strength:
Manufacturer: Open Biome

#2 Name:
Strength:
Manufacturer:

2. Dose or Amount	Frequency	Route
#1 250 mL	1 time	via colonoscopy to cecum
#2		

3. Dates of Use (If unknown, give duration) from/to (or best estimate)

#1 12/16/2015
#2

4. Diagnosis or Reason for Use (Indication)

#1 C diff colitis
#2

5. Event Abated After Use Stopped or Dose Reduced?

#1 ☐ Yes ☐ No ☒ Doesn't Apply
#2 ☐ Yes ☐ No ☒ Doesn't Apply

6. Lot # | Expiration Date

#1 (b) (6) 6/19/16
#2 #2

6. Event Reappeared After Reintroduction?

#1 ☐ Yes ☐ No ☒ Doesn't Apply
#2 ☐ Yes ☐ No ☒ Doesn't Apply

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name: N/A

2. Common Device Name

2b. Procode: CTU

3. Manufacturer Name, City and State

DEC 24 2015

4. Model #	Lot #	6. Operator of Device
		☐ Health Professional
Catalog #	Expiration Date (mm/dd/yyyy)	☐ Lay User/Patient
		☐ Other:
Serial #	Unique Identifier (UDI) #	

7. If Implanted, Give Date (mm/dd/yyyy)

7. If Explanted, Give Date (mm/dd/yyyy)

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

NA

G. REPORTER (See confidentiality section on back)

(b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☒ Yes ☐ No	Physician	☒ Manufacturer
		☐ User Facility
5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☐		☐ Distributor/Importer

PLEASE TYPE OR USE BLACK INK

FORM FDA 3500 (2/13) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

DSS

DEC 24 2015

Individual Case Safety Report

(b) (6) >> 18003320178 CBER P 1/2

11905619-01-00-01

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See PRA statement on reverse.

The FDA Safety Information and Adverse Event Reporting Program

TARY reporting of product problems and product use errors

Page 1 of 1

FDA USE ONLY
Triage unit sequence #: 631853

A. PATIENT INFORMATION

(b) (6)
In confidence

2. Age at Time of Event or Date of Birth: 73 (b) (6)

3. Sex: ☑ Female ☐ Male

4. Weight: or 68.58 kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem (e.g., defective/malfunction)
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event (Check all that apply)
☐ Death (mm/dd/yyyy) ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☑ Hospitalization - initial or prolonged ☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (mm/dd/yyyy): 12/19/2015

4. Date of this Report (mm/dd/yyyy): 1-7-16

5. Describe Event, Problem or Product Use Error

Fever p Fecal Transplant

6. Relevant Tests/Laboratory Data, Including Dates

CTU
JAN - 8 2016

JAN - 8 2016
CTU

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)

Multiple Myeloma

C. PRODUCT AVAILABILITY

Product Available for Evaluation? (Do not send product to FDA)
☑ Yes ☐ No ☐ Returned to Manufacturer on: (mm/dd/yyyy)

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer (from product label)

#1 Name: Open Biome
Strength:
Manufacturer: Fecal Microbiota Preparation

#2 Name:
Strength:
Manufacturer:

2. Dose or Amount	Frequency	Route
#1 250 cc	1 x	via colonoscopy
#2		

3. Dates of Use (If unknown, give duration) from/to (or best estimate)
#1 12/17/15 1 day
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Diagnosis or Reason for Use (Indication)
#1 Refractory C. Difficile
#2

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date	9. NDC # or Unique ID
#1 (b) (6)	#1 6/14/16	
#2	#2	

E. SUSPECT MEDICAL DEVICE

1. Brand Name: NA

2. Common Device Name: 2b. Procode:

3. Manufacturer Name, City and State:

4. Model #: Lot #: 6. Operator of Device: ☐ Health Professional
Catalog #: Expiration Date (mm/dd/yyyy): ☐ Lay User/Patient
Serial #: Unique Identifier (UDI) #: ☐ Other:

8. If Implanted, Give Date (mm/dd/yyyy): 9. If Explanted, Give Date (mm/dd/yyyy):

10. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No

11. If Yes to Item No. 10, Enter Name and Address of Reprocessor:

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

G. REPORTER (See confidentiality agreement on back)

(b) (6)

2. Health Professional? ☑ Yes ☐ No
3. Occupation: Gastroenterologist
4. Also Reported to: ☑ Manufacturer ☐ User Facility ☐ Distributor/Importer
5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☒

PLEASE TYPE OR USE BLACK INK

FORM FDA 3500 (2/13) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

CBER

Individual Case Safety Report

12105458-01-00-01

eporting of problems and tors

Form Approved: OMB No. 0910-0291, Expires: 9/30/2018
See PRA statement on reverse.

FDA USE ONLY
Triage unit sequence # 639170
FDA Rec. Date

Note: For date prompts of "dd-mmm-yyyy" please use 2-digit day, 3-letter month abbreviation, and 4-digit year; for example, 01-Jul-2015.

A. PATIENT INFORMATION

1. Patient Identifier (b) (6) In Confidence
2. Age 86 ☐ Year(s) ☐ Month(s) ☐ Week(s) ☐ Days(s) or Date of Birth (e.g., 08 Feb 1925) __-___-____
3. Sex ☐ Female ☒ Male
4. Weight ____ ☐ lb ☐ kg

5.a. Ethnicity (Check single best answer)
☐ Hispanic/Latino
☒ Not Hispanic/Latino

5.b. Race (Check all that apply)
☐ Asian ☐ American Indian or Alaskan Native
☐ Black or African American ☐ White
☐ Native Hawaiian or Other Pacific Islander

B. ADVERSE EVENT, PRODUCT PROBLEM

1. Check all that apply
☒ Adverse Event ☐ Product Problem (e.g., defects/malfunctions)
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcome Attributed to Adverse Event (Check all that apply)
☒ Death Include date (dd-mmm-yyyy): (b) (6)
☐ Life-threatening ☐ Disability or Permanent Damage
☐ Hospitalization – initial or prolonged ☐ Congenital Anomaly/Birth Defects
☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (dd-mmm-yyyy): 04-Feb-2016
4. Date of this Report (dd-mmm-yyyy): 05-Feb-2016

5. Describe Event, Problem or Product Use Error
86 y/o M with glaucoma/legally blind, and atrial fibrillation, who was admitted (b) (6) with severe, complicated C difficile colitis. He underwent fecal transplant x 2 (1/21/16 and 01/28/16). Leukocytosis improved. Stools became formed. On (b) (6) he declined with hypotension, hypoxemia. Expired on (b) (6) Blood culture grew gram negative rods.

6. Relevant Tests/Laboratory Data, Including Dates
Blood culture 02/03/2016: Klebsiella pneumonia

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)
atrial fibrillation, hypertension, glaucoma

C. PRODUCT AVAILABILITY

2. Product Available for Evaluation? (Do not send product to FDA)
☐ Yes ☒ No ☐ Returned to Manufacturer on (dd-mmm-yyyy) __-___-____

D. SUSPECT PRODUCTS

1. Name, Manufacturer/Compounder, Strength (from product label)

#1 – Name and Strength: Donor stool	#1 – NDC # or Unique ID: (b) (6)
#1 – Manufacturer/Compounder: Openbiome	#1 – Lot #: DSS FEB 22 2016
#2 – Name and Strength: Donor stool	#2 – NDC # or Unique ID
#2 – Manufacturer/Compounder: Openbiome	#2 – Lot #: (b) (6)

3. Dose or Amount / Frequency / Route

	Dose or Amount	Frequency	Route
#1	250 cc	once	sigmoidoscopy
#2	250 cc	once	enema

4. Dates of Use (From/To for each) (If unknown, give duration, or best estimate) (dd-mmm-yyyy)
#1 01/21/2016
#2 01/28/2016

5. Diagnosis or Reason for Use (Indication)
#1 severe C difficile infection
#2

9. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☐ No ☒ Doesn't apply
#2 ☐ Yes ☐ No ☒ Doesn't apply

10. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☒ Doesn't apply
#2 ☐ Yes ☐ No ☒ Doesn't apply

6. Is the Product Compounded?
#1 ☐ Yes ☒ No
#2 ☐ Yes ☒ No

7. Is the Product Over-the-Counter?
#1 ☐ Yes ☒ No
#2 ☐ Yes ☒ No

8. Expiration Date (dd-mmm-yyyy)
#1 __-___-____ #2 __-___-____

E. SUSPECT MEDICAL DEVICE

1. Brand Name
2. Common Device Name: CTU
2b. Procode
3. Manufacturer Name, City and St: FEB 22 2016
4. Model #
Lot #
Catalog #
Expiration Date (dd-mmm-yyyy) __-___-____
Serial #
Unique Identifier (UDI) #
5. Operator of Device ☐ Health Professional ☐ Lay User/Patient ☐ Other
6. If Implanted, Give Date (dd-mmm-yyyy) __-___-____
7. If Explanted, Give Date (dd-mmm-yyyy) __-___-____
8. Is this a single-use device that was reprocessed and reused on a patient? ☐ Yes ☐ No
9. If Yes to Item 8, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (Exclude treatment of event)

G. REPORTER (See confidentiality section on back)

1. Name and Address
(b) (6)

2. Health Professional? ☒ Yes ☐ No
3. Occupation: Physician
4. Also Reported to: ☒ Manufacturer/Compounder ☐ User Facility ☐ Distributor/Importer
5. If you do NOT want your identity disclosed to the manufacturer, please mark this box: ☐

PLEASE TYPE OR USE BLACK INK

 Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

Individual Case Safety Report

12166980-01-00-01

ARY reporting of roduct problems and : use errors — CBER

Form Approved: OMB No. 0910-0291, Expires: 9/30/2018
See PRA statement on reverse.

FDA USE ONLY
Triage unit sequence #
FDA Rec. Date 042408

Note: For date prompts of "dd-mmm-yyyy" please use 2-digit day, 3-letter month abbreviation, and 4-digit year; for example, 01-Jul-2015.

A. PATIENT INFORMATION

1. Patient Identifier: (b) (6) In Confidence
2. Age: 86 ☒ Year(s) ☐ Month(s) ☐ Week(s) ☐ Days(s) — or Date of Birth (e.g., 08 Feb 1925)
3. Sex: ☐ Female ☒ Male
4. Weight: ☐ lb ☐ kg

5.a. Ethnicity (Check single best answer): ☐ Hispanic/Latino ☒ Not Hispanic/Latino

5.b. Race (Check all that apply): ☐ Asian ☐ American Indian or Alaskan Native ☐ Black or African American ☒ White ☐ Native Hawaiian or Other Pacific Islander

B. ADVERSE EVENT, PRODUCT PROBLEM

1. Check all that apply
☒ Adverse Event ☐ Product Problem (e.g., defects/malfunctions)
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcome Attributed to Adverse Event (Check all that apply)
☒ Death Include date (dd-mmm-yyyy): (b) (6)
☐ Life-threatening ☐ Disability or Permanent Damage
☐ Hospitalization – Initial or prolonged ☐ Congenital Anomaly/Birth Defects
☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (dd-mmm-yyyy): 13-Jan-2015
4. Date of this Report (dd-mmm-yyyy): 26-Feb-2016

5. Describe Event, Problem or Product Use Error
Patient will multiple comorbidities; severe C difficile infection. Treated with FMT. Though the C difficile improved, he continued to suffer from cardiac and respiratory issues as well as compromised neurologically from recent hemorrhagic stroke. Was transferred to hospice and expired on (b) (6)

6. Relevant Tests/Laboratory Data, Including Dates
WBC 36,000, C diff + stools. Abdominal CT-fluid filled colon (at admission (b) (6)

Sigmoidoscopy on 01/11/16-mild pseudomembranes

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)
hemorrhagic CVA, PEG tube placement, mitral valve replacement/mechanical valve, myelodysplastic syndrome

C. PRODUCT AVAILABILITY

2. Product Available for Evaluation? (Do not send product to FDA)
☒ Yes ☐ No ☐ Returned to Manufacturer on (dd-mmm-yyyy)

D. SUSPECT PRODUCTS

1. Name, Manufacturer/Compounder, Strength (from product label)

#1 – Name and Strength: FMT	#1 – NDC # or Unique ID
#1 – Manufacturer/Compounder: Openbiome DSS	#1 – Lot #: (b) (6)
#2 – Name and Strength: FMT MAR 09 2016	#2 – NDC # or Unique ID
#2 – Manufacturer/Compounder	#2 – Lot #: (b) (6)

3. Dose or Amount	Frequency	Route
#1 250 cc		via sigmoidoscopy
#2 250 cc		via sigmoidoscopy

4. Dates of Use (From/To for each) (If unknown, give duration, or best estimate) (dd-mmm-yyyy)
#1 06/jan/2016
#2 11/jan/2016

5. Diagnosis or Reason for Use (indication)
#1 severe, refractory C difficile
#2

9. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☐ No ☒ Doesn't apply
#2 ☐ Yes ☐ No ☒ Doesn't apply

10. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☒ Doesn't apply
#2 ☐ Yes ☐ No ☒ Doesn't apply

6. Is the Product Compounded?	7. Is the Product Over-the-Counter?
#1 ☐ Yes ☒ No	#1 ☐ Yes ☒ No
#2 ☐ Yes ☐ No	#2 ☐ Yes ☒ No

8. Expiration Date (dd-mmm-yyyy)
#1 __-___-____ #2 __-___-____

E. SUSPECT MEDICAL DEVICE

1. Brand Name
2. Common Device Name — CTU — 2b. Procode
3. Manufacturer Name, City and State — MAR – 9 2016

4. Model #	Lot #	5. Operator of Device: ☐ Health Professional ☐ Lay User/Patient ☐ Other
Catalog #	Expiration Date (dd-mmm-yyyy) __-___-____	
Serial #	Unique Identifier (UDI) #	

6. If Implanted, Give Date (dd-mmm-yyyy) __-___-____
7. If Explanted, Give Date (dd-mmm-yyyy) __-___-____

8. Is this a single-use device that was reprocessed and reused on a patient? ☐ Yes ☐ No

9. If Yes to Item 8, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (Exclude treatment of event)

G. REPORTER (See confidentiality section on back)

1. Name and Address

(b) (6)

2. Health Professional? ☒ Yes ☐ No
3. Occupation: physician
4. Also Reported to: ☒ Manufacturer/Compounder ☐ User Facility ☐ Distributor/Importer
5. If you do NOT want your identity disclosed to the manufacturer, please mark this box: ☐

PLEASE TYPE OR USE BLACK INK

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

J Woo

Individual Case Safety Report

12203638-01-00-01

CBER

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See PRA statement on reverse.

MANDATORY reporting of product problems and product use errors

The FDA Safety Information and Adverse Event Reporting Program

Page 1 of 3

FDA USE ONLY
Triage unit sequence #: 644975

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
In confidence	(b) (6)	☒ Female ☐ Male	____ lb or 70.3 kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☒ Adverse Event ☐ Product Problem (e.g., defects/malfunctions)
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event (Check all that apply): OTHER
☐ Death: ____ (mm/dd/yyyy) ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - initial or prolonged ☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (mm/dd/yyyy)	4. Date of this Report (mm/dd/yyyy)
3/4/2016	

5. Describe Event, Problem or Product Use Error

- vomiting 7 hours after FMT; premedicated with PPI and ondansetron

6. Relevant Tests/Laboratory Data, Including Dates

CTU MAR 22 2016 N/A DSS MAR 22 2016

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)

57 yo female, with recurrent c-diff, who developed SELF-LIMITED vomiting, 7h after FMT

C. PRODUCT AVAILABILITY

Product Available for Evaluation? (Do not send product to FDA)
☐ Yes ☒ No ☐ Returned to Manufacturer on: ____ (mm/dd/yyyy)

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer (from product label)
#1 Name: FMT bottle (b) (6)
Strength:
Manufacturer: OPEN BIOME

#2 Name:
Strength:
Manufacturer:

2. Dose or Amount	Frequency	Route
#1 30 ml	x 1	NGT
#2		

3. Dates of Use (If unknown, give duration) from/to (or best estimate)
#1 3/4/16
#2

4. Diagnosis or Reason for Use (Indication)
#1 C-diff
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☐ No ☒ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. [illegible] Expiration Date
(b) (6)
#2 #2

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☒ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name: N/A

2. Common Device Name	2b. Procode

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date (mm/dd/yyyy)	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Unique Identifier (UDI) #	

6. If Implanted, Give Date (mm/dd/yyyy)	7. If Explanted, Give Date (mm/dd/yyyy)

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)
N/A

G. REPORTER (See confidentiality section on back)

(b) (6)

2. Health Professional? ☒ Yes ☐ No
3. Occupation: PHYSICIAN
5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☒

☒ Manufacturer ☐ User Facility ☐ Distributor/Importer

PLEASE TYPE OR USE BLACK INK

FORM FDA 3500 (2/13)

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

Individual Case Safety Report

12240892-01-00-01

Health
l Report
.Y reporting of
uct problems and
se errors

Form Approved: OMB No. 0910-0291, Expires: 09/30/2018
See PRA statement on reverse.

The FDA Safety Information and Adverse Event Reporting Program

FDA USE ONLY	
Triage unit sequence #	647818
FDA Rec. Date	

Note: For date prompts of "dd-mmm-yyyy" please use 2-digit day, 3-letter month abbreviation, and 4-digit year; for example, 01-Jul-2015.

A. PATIENT INFORMATION

1. Patient Identifier: (b) (6) In Confidence
2. Age: ____ ☐ Year(s) ☐ Month(s) ☐ Week(s) ☐ Day(s) or Date of Birth (dd-mmm-yyyy): (b) (6) (e.g. 08 Feb 1925)
3. Sex: ☐ Female ☑ Male
4. Weight: 73 ☐ lb ☑ kg

5.a. Ethnicity (Check single best answer): ☐ Hispanic/Latino ☑ Not Hispanic/Latino

5.b. Race (Check all that apply): ☐ Asian ☐ American Indian or Alaskan Native ☑ Black or African American ☐ White ☐ Native Hawaiian or Other Pacific Islander

B. ADVERSE EVENT, PRODUCT PROBLEM

1. Check all that apply: ☑ Adverse Event ☐ Product Problem (e.g., defects/malfunctions) ☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcome Attributed to Adverse Event (Check all that apply): ☐ Death Include date (dd-mmm-yyyy): ____ ☐ Life-threatening ☑ Hospitalization - Initial or prolonged ☑ Other Serious (Important Medical Events) ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices) ☐ Disability or Permanent Damage ☐ Congenital Anomaly/Birth Defects

3. Date of Event (dd-mmm-yyyy): 01-Apr-2016

4. Date of this Report (dd-mmm-yyyy): 04-Apr-2016

5. Describe Event, Problem or Product Use Error: See additional page(s) for complete text.

6. Relevant Tests/Laboratory Data, Including Dates:

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, pregnancy, smoking and alcohol use, liver/kidney problems, etc.): See additional page(s) for complete text.

C. PRODUCT AVAILABILITY

2. Product Available for Evaluation? (Do not send product to FDA): ☐ Yes ☑ No ☐ Returned to Manufacturer on: ____ (dd-mmm-yyyy)

D. SUSPECT PRODUCTS

1. Name, Manufacturer/Compounder, Strength (from product label)

#1 - Name and Strength: FMT (b) (4)	#1 - NDC # or Unique ID: (b) (6)
#1 - Manufacturer/Compounder: OpenBiome	#1- Lot #
#2 - Name and Strength	#2 - NDC # or Unique ID
#2 - Manufacturer/Compounder	#2- Lot #

DS

	Dose or Amount	Frequency	Route
#1	30 (b) (4)	once	oral
#2			

4. Dates of Use (From/To for each) (If unknown, give duration, or best estimate) (dd-mmm-yyyy): #1 24-Mar-2016 ~ 24-Mar-2016 #2

5. Diagnosis or Reason for Use (indication): #1 recurrent C. difficile colitis #2

6. Is the Product Compounded? #1 ☐ Yes ☐ No #2 ☐ Yes ☐ No

7. Is the Product Over-the-Counter? #1 ☐ Yes ☑ No #2 ☐ Yes ☐ No

8. Expiration Date (dd-mmm-yyyy): #1 13-Apr-2016 #2

9. Event Abated After Use Stopped or Dose Reduced? #1 ☐ Yes ☐ No ☑ Doesn't apply #2 ☐ Yes ☐ No ☐ Doesn't apply

10. Event Reappeared After Reintroduction? #1 ☐ Yes ☐ No ☑ Doesn't apply #2 ☐ Yes ☐ No ☐ Doesn't apply

E. SUSPECT MEDICAL DEVICE

1. Brand Name: CTU

2. Common Device Name: APR - 5 2016 2b. Procode:

3. Manufacturer Name, City and State:

4. Model #: Lot #: 5. Operator of Device: ☐ Health Professional ☐ Lay User/Patient ☐ Other:

Catalog #: Expiration Date (dd-mmm-yyyy):

Serial #: Unique Identifier (UDI) #:

6. If Implanted, Give Date (dd-mmm-yyyy): 7. If Explanted, Give Date (dd-mmm-yyyy):

8. Is this a single-use device that was reprocessed and reused on a patient? ☐ Yes ☐ No

9. If Yes to Item 8, Enter Name and Address of Reprocessor:

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (Exclude treatment of event):

G. REPORTER (See confidentiality section on back)

1. Name and Address: (b) (6)

2. Health Professional? ☑ Yes ☐ No

3. Occupation: Medical Doctor (Physician)

4. Also Reported to: ☑ Manufacturer/ Compounder ☐ User Facility ☐ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, please mark this box: ☐

PLEASE TYPE OR USE BLACK INK

FORM FDA 3500 (10/15) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

APR 5 2016

Individual Case Safety Report

12240892-01-00-02

647818

The patient received an OpenBiome FMT (b) (4) fecal transplant on 3/24/2016. He was kept in the hospital until (b) (6) His diarrhea resolved completely prior to discharge. He was afebrile and without abdominal pain/tenderness at discharge. In addition, he had no evidence of leukocytosis or renal dysfunction during this hospitalization. Following discharge, the diarrhea recurred and he developed severe abdominal pain. He returned to the hospital on (b) (6) with recurrent C. diff, pancolitis and colonic perforation as well as secondary psoas abscess complicated by necrotizing fasciitis. He underwent exploratory laparotomy, subtotal colectomy with end ileostomy and debridement of the left thigh wound on (b) (6) He's currently in the Intensive Care Unit on pressors and intubated. He is making minimal urine output and may require dialysis.

B.6. **Relevant Tests/Laboratory Data, Including Dates** *(continued)*

B.7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g. allergies, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)*

47 year-old male from (b) (6) chronic hepatitis B (on (b) (6), presumed disseminated MAC, latent TB infection, prior CMV viremia and stage 4 DLBCL (diagnosed in 8/2015, s/p 3 cycles of R-EPOCH most recently in 1/2016, in complete remission in 11/2015 + high-dose methotrexate). He received a fecal transplant in the setting of his third episode of C. difficile colitis.

F. **Concomitant Medical Products and Therapy Dates (Exclude treatment of event)** *(continued)*

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details

Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500
Priority	Routine		
FDA Received Date	01-Nov-2017	CTU Received Date	01-Nov-2017
CTU Triage Date			
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	☑ CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)		

Contact

Case Reporter	First Name	Last Name	Email Address	Phone
☑	(b) (6)			

A. PATIENT INFORMATION

Patient Identifier (In Confidence)	(b) (6)
Age	38 Year(s)
Date of Birth	
Sex	Female
Weight	67.1 kg(s)
Ethnicity (Check single best answer)	Hispanic/Latino
Race (Check all that apply)	☐ Asian ☐ American Indian or Alaskan Native ☐ Black or African American ☑ White ☐ Native Hawaiian or Other Pacific Islander

B. ADVERSE EVENT, PRODUCT PROBLEM

Check all that apply	☑ Adverse Event ☐ Product Use Error ☐ Product Problem (e.g., defects/malfunctions) ☐ Problem with Different Manufacturer of Same Medicine
Outcome Attributed to Adverse Event (Check all that apply)	☐ Death ☐ Life-threatening ☐ Hospitalization - initial or prolonged ☐ Other Serious (Important Medical Events) ☐ Disability or Permanent Damage ☐ Congenital Anomaly/Birth Defects ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
Date of Death	
Date of Event	28-Oct-2017
Date of this Report	01-Nov-2017

Describe Event, Problem or Product Use Error

Describe Event, Problem, or Product Use Error: Patient reports abdominal discomfort, bloating, and blood per rectum 10 days after Fecal transplant.

Relevant Tests/Laboratory Data, Including Dates

Other Relevant History, Including Preexisting Medical Conditions

Participant has pre-existing chronic pouchitis and history of ulcerative colitis.

C. PRODUCT AVAILABILITY

Product Available for Evaluation? (Do not send product to FDA)	No
Returned to Manufacturer on	

D. SUSPECT PRODUCTS

1 of 1

Product Name	Fecal Transplant		
Strength		If Other	
Manufacturer/Compounder			
NDC# or Unique ID			
Lot Number			
Dose or Amount		If Other	
Frequency	Other	If Other	once
Route	Rectal	If Other	
Therapy Start Date	18-Oct-2017		
Therapy End Date	18-Oct-2017		
Therapy Duration		If Other	
Diagnosis or Reason for Use (indication)	Chronic Pouchitis		
Is the Product Compounded?			
Is the Product Over-the-Counter?			
Expiration Date	18-Oct-2017		
Event Abated After Use Stopped or Dose Reduced?	Doesn't Apply		
Event Reappeared after Reintroduction ?	Doesn't Apply		

E. SUSPECT MEDICAL DEVICE

Brand Name	
Common Device Name	
Procode	
Manufacturer Name	

City	
State	
Model #	
Lot #	
Catalog #	
Expiration Date	
Serial #	
Unique Identifier (UDI) #	
Operator of Device	☐ Health Professional ☐ Lay User/Patient ☐ Other
Other	
If Implanted, Give Date	
If Explanted, Give Date	
Is this a single-use device that was reprocessed and reused on a patient?	
If Yes for the above field, Enter Name and Address of Reprocessor	

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

CONCOMITANT MEDICAL PRODUCT DESCRIPTION

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS 1 of 1

Product Name			
Strength		If Other	
Therapy Start Date			
Therapy End Date			

G. REPORTER

Last Name	(b) (6)		
First Name			
Address			
City			
State/Province/Region			
Country			
ZIP/Postal Code			
Phone			
Email			
Health Professional?	Yes		
Occupation	Physician	If Other	

	Also Reported to	☐ Manufacturer/Compounder ☐ User Facility ☐ Distributor/Importer	
	If you do NOT want your identity disclosed to the manufacturer, please mark this box:	☐	

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details

Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500
Priority	Routine		
FDA Received Date	15-Dec-2017	CTU Received Date	15-Dec-2017
CTU Triage Date			
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	☑ CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)		

Contact

Case Reporter	First Name	Last Name	Email Address	Phone
☑	(b) (6)			

A. PATIENT INFORMATION

Patient Identifier (In Confidence)	(b) (6)
Age	38 Year(s)
Date of Birth	
Sex	Female
Weight	67.6 kg(s)
Ethnicity (Check single best answer)	Hispanic/Latino
Race (Check all that apply)	☐ Asian ☐ American Indian or Alaskan Native ☐ Black or African American ☑ White ☐ Native Hawaiian or Other Pacific Islander

B. ADVERSE EVENT, PRODUCT PROBLEM

Check all that apply	☑ Adverse Event ☐ Product Use Error ☐ Product Problem (e.g., defects/malfunctions) ☐ Problem with Different Manufacturer of Same Medicine
Outcome Attributed to Adverse Event (Check all that apply)	☐ Death ☐ Life-threatening ☐ Hospitalization - initial or prolonged ☐ Other Serious (Important Medical Events) ☐ Disability or Permanent Damage ☐ Congenital Anomaly/Birth Defects ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
Date of Death	
Date of Event	20-Nov-2017
Date of this Report	15-Dec-2017

Describe Event, Problem or Product Use Error

Describe Event, Problem, or Product Use Error: Participant reported experiencing increased nausea and stool frequency in clinic during her follow up visit. Participant reports having decreased energy and infrequent appetite. Participant denies seeing any blood in her stool. Participant also stated that these symptoms have been occurring since receiving the fecal transplant.

Relevant Tests/Laboratory Data, Including Dates

Other Relevant History, Including Preexisting Medical Conditions

Participant is allergic to gadolinium containing compounds, morphine, and Zofran. She has been diagnosed with ulcerative colitis associated pouchitis for which this intervention was indicated.

C. PRODUCT AVAILABILITY

Product Available for Evaluation? (Do not send product to FDA)	No
Returned to Manufacturer on	

D. SUSPECT PRODUCTS

1 of 1

Product Name	Fecal Microbiota			
Strength		If Other		
Manufacturer/Compounder				
NDC# or Unique ID				
Lot Number				
Dose or Amount		If Other		
Frequency	Other	If Other	Administered once	
Route	Rectal	If Other		
Therapy Start Date	18-Oct-2017			
Therapy End Date	18-Oct-2017			
Therapy Duration		If Other		
Diagnosis or Reason for Use (indication)	Ulcerative colitis associated pouchitis			
Is the Product Compounded?				
Is the Product Over-the-Counter?				
Expiration Date				
Event Abated After Use Stopped or Dose Reduced?	Doesn't Apply			
Event Reappeared after Reintroduction ?	Doesn't Apply			

E. SUSPECT MEDICAL DEVICE

Brand Name	
Common Device Name	
Procode	

Manufacturer Name	
City	
State	
Model #	
Lot #	
Catalog #	
Expiration Date	
Serial #	
Unique Identifier (UDI) #	
Operator of Device	☐ Health Professional ☐ Lay User/Patient ☐ Other
Other	
If Implanted, Give Date	
If Explanted, Give Date	
Is this a single-use device that was reprocessed and reused on a patient?	
If Yes for the above field, Enter Name and Address of Reprocessor	

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

CONCOMITANT MEDICAL PRODUCT DESCRIPTION

Fecal Microbiota Transplant-10/18/2017-10/18/2017

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS 1 of 1

Product Name			
Strength		If Other	
Therapy Start Date			
Therapy End Date			

G. REPORTER

Last Name	(b) (6)		
First Name			
Address			
City			
State/Province/Region			
Country			
ZIP/Postal Code			
Phone			
Email			
Health Professional?	Yes		
Occupation	Physician	If Other	

	Also Reported to	☐ Manufacturer/Compounder ☐ User Facility ☐ Distributor/Importer	
	If you do NOT want your identity disclosed to the manufacturer, please mark this box:	☐	

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details

Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500
Priority	High		
FDA Received Date	19-Dec-2017	CTU Received Date	19-Dec-2017
CTU Triage Date			
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	☑ CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)		

Contact

Case Reporter	First Name	Last Name	Email Address	Phone
☑	(b) (6)			

A. PATIENT INFORMATION

Patient Identifier (In Confidence)	(b) (6)
Age	
Date of Birth	(b) (6)
Sex	Female
Weight	62.7 kg(s)
Ethnicity (Check single best answer)	Hispanic/Latino
Race (Check all that apply)	☐ Asian ☐ American Indian or Alaskan Native ☐ Black or African American ☑ White ☐ Native Hawaiian or Other Pacific Islander

B. ADVERSE EVENT, PRODUCT PROBLEM

Check all that apply	☑ Adverse Event ☐ Product Use Error ☐ Product Problem (e.g., defects/malfunctions) ☐ Problem with Different Manufacturer of Same Medicine
Outcome Attributed to Adverse Event (Check all that apply)	☐ Death ☐ Life-threatening ☐ Hospitalization - initial or prolonged ☐ Other Serious (Important Medical Events) ☐ Disability or Permanent Damage ☐ Congenital Anomaly/Birth Defects ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
Date of Death	
Date of Event	28-Oct-2017
Date of this Report	19-Dec-2017

Describe Event, Problem or Product Use Error

Describe Event, Problem, or Product Use Error: Patient received a fecal microbial transplant on October 18, 2017 for chronic pouchitis symptoms which included abdominal pain, frequency and urgency. She reported abdominal discomfort, bloating and blood per rectum 10 days after fecal transplant (This was reported through MedWatch on 10/31/2017). She has continued to have some abdominal discomfort associated with nausea that she has dealt with through diet modification. Her vital signs and weight remains unchanged. This is an update for her follow up clinic visit which occurred on November 20, 2017 but we filled out the wrong reporting form. I received notice from Dr. Qun Wang yesterday that we submitted the wrong reporting form.

Relevant Tests/Laboratory Data, Including Dates

Chemistry and CBC normal 12/1/2017: Na 139, Potassium 4, Cl 105, CO2 23, BUN 12, Cr 0.63, glucose 89 CBC 6.3, hbg 14.3, hematocrit 40.5, platelets 370

Other Relevant History, Including Preexisting Medical Conditions

Patient with a pre-existing condition of chronic pouchitis with abdominal pain, urgency, and frequency, and history of ulcerative colitis.

C. PRODUCT AVAILABILITY

Product Available for Evaluation? (Do not send product to FDA)	Yes
Returned to Manufacturer on	

D. SUSPECT PRODUCTS

1 of 1

Product Name	Fecal transplant			
Strength		If Other		
Manufacturer/Compounder				
NDC# or Unique ID				
Lot Number				
Dose or Amount	250 ml millilitre(s)	If Other		
Frequency	Other	If Other	once	
Route	Rectal	If Other		
Therapy Start Date	18-Oct-2017			
Therapy End Date	18-Oct-2017			
Therapy Duration		If Other		
Diagnosis or Reason for Use (indication)	ulcerative colitis associated chronic pouchitis			
Is the Product Compounded?	Yes			
Is the Product Over-the-Counter?				
Expiration Date				
Event Abated After Use Stopped or Dose Reduced?	Doesn't Apply			
Event Reappeared after Reintroduction ?	Doesn't Apply			

E. SUSPECT MEDICAL DEVICE

Brand Name	
Common Device Name	
Procode	

Manufacturer Name	
City	
State	
Model #	
Lot #	
Catalog #	
Expiration Date	
Serial #	
Unique Identifier (UDI) #	
Operator of Device	☐ Health Professional ☐ Lay User/Patient ☐ Other
Other	
If Implanted, Give Date	
If Explanted, Give Date	
Is this a single-use device that was reprocessed and reused on a patient?	
If Yes for the above field, Enter Name and Address of Reprocessor	

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

CONCOMITANT MEDICAL PRODUCT DESCRIPTION

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS 1 of 1

Product Name			
Strength		If Other	
Therapy Start Date			
Therapy End Date			

G. REPORTER

Last Name	(b) (6)		
First Name			
Address			
City			
State/Province/Region			
Country			
ZIP/Postal Code			
Phone			
Email			
Health Professional?	Yes		
Occupation	Physician	If Other	

	Also Reported to	☐ Manufacturer/Compounder ☐ User Facility ☐ Distributor/Importer	
	If you do NOT want your identity disclosed to the manufacturer, please mark this box:	☐	

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details

Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500
Priority	High		
FDA Received Date	09-Jan-2018	CTU Received Date	09-Jan-2018
CTU Triage Date			
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	☑ CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)		

Contact

Case Reporter	First Name	Last Name	Email Address	Phone
☑	(b) (6)			

A. PATIENT INFORMATION

Patient Identifier (In Confidence)	(b) (6)
Age	
Date of Birth	(b) (6)
Sex	Female
Weight	62.7 kg(s)
Ethnicity (Check single best answer)	Hispanic/Latino
Race (Check all that apply)	☐ Asian ☐ American Indian or Alaskan Native ☐ Black or African American ☑ White ☐ Native Hawaiian or Other Pacific Islander

B. ADVERSE EVENT, PRODUCT PROBLEM

Check all that apply	☑ Adverse Event ☐ Product Use Error ☐ Product Problem (e.g., defects/malfunctions) ☐ Problem with Different Manufacturer of Same Medicine
Outcome Attributed to Adverse Event (Check all that apply)	☐ Death ☐ Life-threatening ☑ Hospitalization - initial or prolonged ☐ Other Serious (Important Medical Events) ☐ Disability or Permanent Damage ☐ Congenital Anomaly/Birth Defects ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
Date of Death	
Date of Event	04-Jan-2018
Date of this Report	09-Jan-2018

Describe Event, Problem or Product Use Error

Describe Event, Problem, or Product Use Error:	Patient received a fecal microbial transplant on October 18, 2017 for chronic pouchitis symptoms which included abdominal pain, frequency and urgency. She reported abdominal discomfort, bloating and blood per rectum 10 days after fecal transplant (This was reported through MedWatch on 10/31/2017). She has continued to have some abdominal discomfort associated with nausea that she has dealt with through diet modification. Her vital signs and weight remains unchanged. (This was also reported previously.) When we called her to schedule her 3 month follow up she stated she was having abdominal pain and was headed to the hospital. She was admitted to the hospital on (b) (6) She was afebrile with normal WBC 6.5. Her WBC and vitals have remained normal. She was treated for recurrent pouchitis with steroids, rifaximin, and budesonide (previous regimen). GI did a flexible sigmoidoscopy and found the pouch to be normal, but a small ulcer at the junction of pouch and ileum.

Relevant Tests/Laboratory Data, Including Dates

(b) (6) WBC 6.5 (b) (6) WBC 5.4 (b) (6) WBC 4.7

Other Relevant History, Including Preexisting Medical Conditions

Patient has a pre-existing condition of chronic pouchitis with abdominal pain, urgency, frequency and history of ulcerative colitis. She was admitted to the hospital in (b) (6) (prior to fecal transplantation) for these symptoms.

C. PRODUCT AVAILABILITY

Product Available for Evaluation? (Do not send product to FDA)	Yes
Returned to Manufacturer on	

D. SUSPECT PRODUCTS 1 of 1

Product Name	Fecal Transplant		
Strength		If Other	
Manufacturer/Compounder			
NDC# or Unique ID			
Lot Number			
Dose or Amount	250 ml millilitre(s)	If Other	
Frequency	Other	If Other	once
Route	Rectal	If Other	
Therapy Start Date	18-Oct-2017		
Therapy End Date	18-Oct-2017		
Therapy Duration		If Other	
Diagnosis or Reason for Use (indication)	chronic pouchitis		
Is the Product Compounded?	Yes		
Is the Product Over-the-Counter?			
Expiration Date			
Event Abated After Use Stopped or Dose Reduced?	Doesn't Apply		
Event Reappeared after Reintroduction ?	Doesn't Apply		

E. SUSPECT MEDICAL DEVICE

Brand Name	

Common Device Name	
Procode	
Manufacturer Name	
City	
State	
Model #	
Lot #	
Catalog #	
Expiration Date	
Serial #	
Unique Identifier (UDI) #	
Operator of Device	☐ Health Professional ☐ Lay User/Patient ☐ Other
Other	
If Implanted, Give Date	
If Explanted, Give Date	
Is this a single-use device that was reprocessed and reused on a patient?	
If Yes for the above field, Enter Name and Address of Reprocessor	

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

CONCOMITANT MEDICAL PRODUCT DESCRIPTION

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS 1 of 1

Product Name			
Strength		If Other	
Therapy Start Date			
Therapy End Date			

G. REPORTER

Last Name	(b) (6)
First Name	
Address	
City	
State/Province/Region	
Country	
ZIP/Postal Code	
Phone	
Email	

	Health Professional?	Yes			
	Occupation	Physician	If Other		
	Also Reported to	☐ Manufacturer/Compounder ☐ User Facility ☐ Distributor/Importer			
	If you do NOT want your identity disclosed to the manufacturer, please mark this box:	☐			

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details

Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	High		
FDA Received Date	13-Mar-2018	CTU Received Date	13-Mar-2018
CTU Triage Date			
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	☑ CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)		

Contact

Case Reporter	First Name	Last Name	Email Address	Phone
☑	(b) (6)			

Section A - About the Problem

What kind of problem was it? (Check all that apply)	☑ Were hurt or had a bad side effect (including new or worsening symptoms) ☐ Used a product incorrectly which could have or led to a problem ☐ Noticed a problem with the quality of the product ☐ Had problems after switching from one product maker to another maker
Did any of the following happen? (Check all that apply)	☐ Hospitalization - admitted or stayed longer ☐ Required help to prevent permanent harm (for medical devices only) ☑ Disability or health problem ☐ Birth defect ☐ Life-threatening ☐ Death ☐ Other serious/important medical incident
Date the problem occurred	01-Dec-2017

Tell us what happened and how it happened (Include as many details as possible)

I am a 62 year old (b) (6), (b) (4) I received my fecal transplan(b) (4)October 12, 2017. December 1 2017 I developed genital HSV!. My serology showed positive IgM and negative IgG. I am married and in a monogamous relationship with my husband. After my diagnosis his serology showed IgG positive for HSVI, IgM negative. He has no history of herpes oral or genital. It would seem he contracted this as a child as does the majority of the population. Open Biome, the source of the fecal(b) (4) does not screen donors for HSVI or HSV2. This incident was reported to the (b) (6), (b) (4) and to Open Biome. I am told that Open Biome feels that there is no possibility that I was infected through the fecal(b) (4) I have two concerns: 1. It is certainly possible, although not previously reported, that HSV1 is transmissible through the fecal product. 2. Even if they did screen their donors there is no way to be sure the feces is from the stated donor as specimens are brought in to the lab, not collected while the donor is in the lab. The product could actually be from anyone. The donors are paid per specimen, so there is financial incentive for fraud. I do think this deserves serious investigation, it is a major public health risk. (b) (6)
(b) (6)

List any relevant tests or laboratory data if you know them (Include dates)

I have all lab data available for you.

Section B - About the Products

1 of 1

Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	fecal transplant (b) (4)			
Name of the company that makes (or compounds) the product	Open Biome			
Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.)	Yes			
Is the Product Over-the-Counter?				
Expiration date				
Lot number				
NDC number				
Strength		If Other		
Quantity		If Other		
Frequency		If Other		
How was it taken or used	Oral	If Other		
Date the person first started taking or using the product	10-Oct-2017			
Date the person stopped taking or using the product				
Did the problem stop after the person reduced the dose or stopped taking or using the product?	No			
Did the problem return if the person started taking or using the product again?				
Do you still have the product in case we need to evaluate it?	No			

Why was the person using the product? (such as what condition was it supposed to treat)

post infectious irritable bowel disease

Section C - About the Medical Device

Name of medical device	
Name of the company that makes the medical device	

Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them)

Model #	
Catalog #	

Serial #	
Lot #	
Unique Identifier (UDI) #	
Expiry Date	
Was someone operating the medical device when the problem occurred?	

For implanted medical devices ONLY (such as pacemakers, breast implants, etc.)

Date the implant was put in		Date the implant was taken out (If relevant)	

Section D - About the Person Who Had the Problem

Person's Initials	(b) (6)
Sex	Female
Age (specify unit of time for age)	62 Year(s)
Date of Birth	
Weight	51.75 kg(s)
Ethnicity (Choose only one)	Not Hispanic/Latino
Race (Check all that apply)	☐ American Indian or Alaskan Native ☐ Native Hawaiian or Other Pacific Islander ☐ Asian ☑ White ☐ Black or African American

List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others)

Please list all allergies (such as to drugs, foods, pollen or others)

sulfa

List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)

List all current prescription medications and medical devices being used

Valtrex 500 mg po qd

List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

1 of 1

	Product Name			
	Strength		If Other	
	Therapy Start Date			
	Therapy End Date			

Section E - About the Person Filling Out This Form

	Last name	(b) (6)
	First name	
	Number/Street	
	City	
	State/Province	
	Country	
	ZIP or Postal code	
	Telephone number	
	Email address	
	Today's date	13-Mar-2018
	Did you report this problem to the company that makes the product (the manufacturer/compounder)?	Yes
	If you do NOT want your identity disclosed to the manufacturer, place an X in this box :	☐

CTU #: FDA-CDER-2018-58042 | Department: CBER | RCT #: RCT-168349 | CTU Triage Date: 23-Jun-2018 | AER #: 15167898 | Total Pages: 1

Reset Form

U.S. Department of Health and Human Services

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

For VOLUNTARY reporting of adverse events, product problems and product use errors

Page 1 of 3

Form Approved: OMB No. 0910-0291, Expires: 9/30/2018
See PRA statement on reverse.

FDA USE ONLY

Triage unit sequence #

FDA Rec. Date

PLEASE TYPE OR USE BLACK INK

Note: For date prompts of "dd-mmm-yyyy" please use 2-digit day, 3-letter month abbreviation, and 4-digit year, for example, 01-Jul-2015.

A. PATIENT INFORMATION

1. Patient Identifier	2. Age	3. Sex	4. Weight
In Confidence	5 ☒ Year(s) ☐ Month(s) ☐ Week(s) ☐ Days(s)	☐ Female ☒ Male	18 ☐ lb ☒ kg
	or Date of Birth (e.g., 08 Feb 1925) __-___-____		

5.a. Ethnicity (Check single best answer)
☐ Hispanic/Latino
☒ Not Hispanic/Latino

5.b. Race (Check all that apply)
☐ Asian ☐ American Indian or Alaskan Native
☐ Black or African American ☐ White
☐ Native Hawaiian or Other Pacific Islander

B. ADVERSE EVENT, PRODUCT PROBLEM

1. Check all that apply
☒ Adverse Event ☐ Product Problem (e.g., defects/malfunctions)
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcome Attributed to Adverse Event (Check all that apply)
☐ Death Include date (dd-mmm-yyyy): __-___-____
☒ Life-threatening ☐ Disability or Permanent Damage
☒ Hospitalization – initial or prolonged ☐ Congenital Anomaly/Birth Defects
☐ Other Serious (Important Medical Events)
☒ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (dd-mmm-yyyy)	4. Date of this Report (dd-mmm-yyyy)
05-24-2018	06-21-2018

5. Describe Event, Problem or Product Use Error

patient presented with fever/sepsis in the setting of central venous catheter 2 days after fecal microbiota transplant (FMT). Clinical presentation suggested sepsis. Stabilized with IV fluids and abx in ED,

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates

Positive blood cultures as per above

(Continue on page 3)

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)

Medically complicated 5 year old with (b) (6) (b) (6) complex congenital heart disease, chronic

(Continue on page 3)

C. PRODUCT AVAILABILITY

2. Product Available for Evaluation? (Do not send product to FDA)
☐ Yes ☒ No ☐ Returned to Manufacturer on (dd-mmm-yyyy) __-___-____

D. SUSPECT PRODUCTS

1. Name, Manufacturer/Compounder, Strength (from product label)

#1 – Name and Strength	#1 – NDC # or Unique ID
open biome FMT 30mL solution	lot (b) (6)
#1 – Manufacturer/Compounder	#1 – Lot #
#2 – Name and Strength	#2 – NDC # or Unique ID
#2 – Manufacturer/Compounder	#2 – Lot #

3. Dose or Amount	Frequency	Route
#1 30mL	once	nasogastric tube
#2		

4. Dates of Use (From/To for each) (If unknown, give duration, or best estimate) (dd-mmm-yyyy)
#1 5/22/2018, one time admin
#2

5. Diagnosis or Reason for Use (indication)
#1
#2

6. Is the Product Compounded?	7. Is the Product Over-the-Counter?
#1 ☐ Yes ☒ No	#1 ☐ Yes ☒ No
#2 ☐ Yes ☐ No	#2 ☐ Yes ☐ No

8. Expiration Date (dd-mmm-yyyy)
#1 __-___-____ #2 __-___-____

9. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☐ No ☒ Doesn't apply
#2 ☐ Yes ☐ No ☐ Doesn't apply

10. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☒ Doesn't apply
#2 ☐ Yes ☐ No ☐ Doesn't apply

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name | 2b. Procode

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date (dd-mmm-yyyy) __-___-____	☐ Health Professional ☐ Lay User/Patient ☐ Other
Serial #	Unique Identifier (UDI) #	

6. If Implanted, Give Date (dd-mmm-yyyy)	7. If Explanted, Give Date (dd-mmm-yyyy)
__-___-____	__-___-____

8. Is this a single-use device that was reprocessed and reused on a patient? ☐ Yes ☐ No

9. If Yes to Item 8, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (Exclude treatment of event)

(Continue on page 3)

G. REPORTER (See confidentiality section on back)

1. Name and Address

(b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☒ Yes ☐ No	Physician	☒ Manufacturer/ Compounder ☐ User Facility ☐ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, please mark this box: ☐

FORM FDA 3500 (10/15) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

Reset Form

CTU #: FDA-~~CBER-CTU-~~2018-90481 | Department: CBER | RCT #: RCT-202754 | CTU Triage Date: 02-Oct-2018 | AER #: 15463533 |

Total Pages: 1

CBER

Form Approved: OMB No. 0910-0291, Expires: 9/30/2018
See PRA statement on reverse.

U.S. Department of Health and Human Services
Food and Drug Administration

MEDWATCH

~~FORM FDA 3500A (10/15)~~

For use by user-facilities, importers, distributors and manufacturers for ~~MANDATORY~~ reporting

Mfr Report #
UF/Importer Report #
FDA Use Only

PLEASE TYPE OR USE BLACK INK

Note: For date prompts of "dd-mmm-yyyy" please use 2-digit day, 3-letter month abbreviation, and 4-digit year; for example, 01-Jul-2015.

A. PATIENT INFORMATION

1. Patient Identifier	2. Age	3. Sex	4. Weight
In Confidence (b) (6)	39 ☐ Year(s) ☐ Month(s) ☐ Week(s) ☐ Days(s) or Date of Birth (e.g., 08-Feb-1925)	☒ Female ☐ Male	☐ lb ☐ kg

5.a. **Ethnicity** *(Check single best answer)*
☐ Hispanic/Latino
☒ Not Hispanic/Latino

5.b. **Race** *(Check all that apply)*
☐ Asian ☐ American Indian or Alaskan Native
☐ Black or African American ☒ White
☐ Native Hawaiian or Other Pacific Islander

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☒ **Adverse Event** and/or ☐ **Product Problem** *(e.g., defects/malfunctions)*

2. **Outcome Attributed to Adverse Event** *(Check all that apply)*
☐ Death *Include date (dd-mmm-yyyy):* __-___-____
☐ Life-threatening
☒ Hospitalization – initial or prolonged
☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
☐ Disability or Permanent Damage
☐ Congenital Anomaly/Birth Defects

3. Date of Event *(dd-mmm-yyyy)*	4. Date of this Report *(dd-mmm-yyyy)*
29-JUN-2018	29-OCT-2018

5. **Describe Event or Problem**
Pt. developed abd pain / vomiting 48 hrs p fecal transplant. Had 2 more diffs overnight before

(Continue on page 3)

6. **Relevant Tests/Laboratory Data, Including Dates**
lipase - 1000, CT c/w pancreatitis

(Continue on page 3)

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*
H/x of Hyperlipidemia
S/P MI x 2 2014

(Continue on page 3)

C. SUSPECT PRODUCT(S)

1. **Name, Manufacturer/Compounder, Strength**

#1 – Name and Strength	#1 – NDC # or Unique ID
Fecal transplant (Stool)	
#1 – Manufacturer/Compounder	#1 – Lot #
Openbiome	
#2 – Name and Strength	#2 – NDC # or Unique ID
#2 – Manufacturer/Compounder	#2 – Lot #

2. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)*

(Continue on page 3)

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

3. Dose	Frequency	Route Used
#1 250 ml	X 1	Colonoscopy
#2 250 ml	X 1	Colonoscopy

4. **Therapy Dates** *(If unknown, give duration)* from/to *(or best estimate)* *(dd-mmm-yyyy)*
#1 21/Feb/2018
#2 26/Jun/2018

5. **Diagnosis for Use** *(Indication)*
#1 Recurrent C. diff
#2 Recurrent C. diff s/p FMT

6. Is the Product Compounded?	7. Is the Product Over-the-Counter?
#1 ☐ Yes ☒ No	#1 ☐ Yes ☒ No
#2 ☐ Yes ☒ No	#2 ☐ Yes ☒ No

8. **Expiration Date** *(dd-mmm-yyyy)*
#1 __-___-____ #2 __-___-____

9. Event Abated After Use Stopped or Dose Reduced?	10. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☒ Doesn't apply	#1 ☐ Yes ☐ No ☒ Doesn't apply
#2 ☐ Yes ☐ No ☒ Doesn't apply	#2 ☐ Yes ☐ No ☒ Doesn't apply

D. SUSPECT MEDICAL DEVICE

1. **Brand Name**

2. **Common Device Name** | 2b. **Procode**

3. **Manufacturer Name, City and State**

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(dd-mmm-yyyy)* __-___-____	☐ Health Professional ☐ Lay User/Patient ☐ Other
Serial #	Unique Identifier (UDI) #	

6. If Implanted, Give Date *(dd-mmm-yyyy)*	7. If Explanted, Give Date *(dd-mmm-yyyy)*
- -	- -

8. **Is this a single-use device that was reprocessed and reused on a patient?** ☐ Yes ☐ No

9. **If Yes to Item 8, Enter Name and Address of Reprocessor**

10. **Device Available for Evaluation?** *(Do not send to FDA)*
☐ Yes ☐ No ☐ Returned to Manufacturer on: __-___-____

11. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)*

(Continue on page 3)

E. INITIAL REPORTER

1. **Name and Address**

(b) (6)

2. Health Professional?	3. Occupation *(Select from list)*	4. Initial Reporter Also Sent Report to FDA
☒ Yes ☐ No	GI MD	☐ Yes ☐ No ☒ Unk